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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,025	01/30/2002	Morton J. Seligman	078061-31851	7891

26345 7590 12/18/2002

GIBBONS, DEL DEO, DOLAN, GRIFFINGER & VECCHIONE
1 RIVERFRONT PLAZA
NEWARK, NJ 07102-5497

EXAMINER

HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/061,025	SELIGMAN, MORTON J.	
	Examiner	Art Unit	
	Mina Haghigheian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____ .
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____ .
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless – (e) the invention was described in-

- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Osbakken et al (US 2002/0061281 A1).

Osbakken teaches aerosolized anti-infectives, anti-inflammatories and decongestants for the treatment of sinusitis. The most common cause for sinusitis is aviral cold or flu that infects the upper respiratory tract and causes obstruction. Fungi are an uncommon cause of sinusitis, but its incidence is increasing (see [0007] and [0008]).

The pharmaceutical compositions include one or more active ingredients such as an anti-infective, anti-inflammatory agent, an antileukotriene, etc (see [0069]).

Antileukotrienes that block leukotrienes at the receptor level have been shown to be relatively safe and effective in the treatment of chronic mild to moderate asthma.

Montelukast sodium is an example of such an antileukotriene, which has been approved for treatment of chronic asthma in patients aged 6 years and older (see [0040]).

Leukotrienes such as montelukast and pranlukast are likely to be alternatives for treating both asthma and rhinosinusitis (see [0041]).

Osbakken also teaches that such compositions preferably are formulated as a liquid (solution, suspension, emulsion, etc) or a powder, that can be mixed with diluent to produce a liquid, in a unit dose or multi-dose vial for aerosol administration to the nasal sinuses for the treatment of sinusitis (see [0070]).

Osbakken discloses that the formulations preferably have a pH in the range of about 3.0 to 8.5, and a NaCl equivalency to the solution or suspension is preferably between about 0.2% NaCl to 3.0% NaCl (see [0073]). To prepare a unit dose, the ingredients of such formulations generally will be dissolved in a solvent such as water or saline solution, in a volume between about 2 and 4 mls (see [0104]).

Osbakken also discloses that fungal infections of the sinuses have a nonspecific clinical presentation, are refractory to standard medical treatment and may produce expansion and erosion of the sinus wall (see [0118]). Inflammation plays an important role in the development of nasal polyps. Leukotrienes are potent chemical mediators important in allergic inflammation. Leukotriene receptor antagonists (anti-leukotrienes) are a new class of drugs which target and block the action of these mediators. Examples of leukotriene receptor antagonists include, but are not limited to, pranlukast, montelukast, etc (see [0125] and [0126]).

Osbakken teaches that montelukast is formulated in dosages of 3.5 mg in 3 ml of sterile water for injection per dose (see [0188]). Table 1, on page 16 discloses a preferable dose range for montelukast to be 0.5 to 15 mg.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghigatian whose telephone number is 703-308-6330. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghigatian
December 12, 2002



MICHAEL G. HARTLEY
PRIMARY EXAMINER